TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

LSA Document #05-321(F)

DIGEST

Adds 410 IAC 15-2.4-2.2, amends 410 IAC 26-1-1, amends 410 IAC 26-1 by adding new definitions, adds 410 IAC 26-6-2, amends 410 IAC 27-1-1, amends 410 IAC 27-1 by adding new definitions, and adds 410 IAC 27-6-2 to require ambulatory outpatient surgical centers, abortion clinics, and birthing centers to implement a medical errors reporting system and report medical errors reporting data to the department. Effective 30 days after filing with the publisher.

410 IAC 15-2.4-2.2	**410 IAC 26-1-13.5**	**410 IAC 27-1-13.4**
410 IAC 26-1-1	**410 IAC 26-1-17.5**	**410 IAC 27-1-13.5**
410 IAC 26-1-3.5	**410 IAC 26-1-17.6**	**410 IAC 27-1-13.6**
410 IAC 26-1-4.6	**410 IAC 26-1-17.8**	**410 IAC 27-1-13.7**
410 IAC 26-1-4.8	**410 IAC 26-1-19**	**410 IAC 27-1-13.8**
410 IAC 26-1-9.5	**410 IAC 26-6-2**	**410 IAC 27-1-13.9**
410 IAC 26-1-12.4	**410 IAC 27-1-1**	**410 IAC 27-1-15.5**
410 IAC 26-1-12.5	**410 IAC 27-1-1.5**	**410 IAC 27-1-16.5**
410 IAC 26-1-12.6	**410 IAC 27-1-2.5**	**410 IAC 27-1-21.5**
410 IAC 26-1-12.7	**410 IAC 27-1-3.5**	**410 IAC 27-1-23**
410 IAC 26-1-12.8	**410 IAC 27-1-9.5**	**410 IAC 27-1-24**
410 IAC 26-1-12.9	**410 IAC 27-1-13.3**	**410 IAC 27-6-2**

SECTION 1. 410 IAC 15-2.4-2.2 IS ADDED TO READ AS FOLLOWS:

410 IAC 15-2.4-2.2 Reporting serious adverse events
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 2.2. (a) The center's quality assessment and improvement program under section 2 of this rule shall include the following:
(1) A process for determining the occurrence of the following serious adverse events within the center:
(A) The following surgical events:
(i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:
(AA) that occur in the course of surgery; or
(BB) whose exigency precludes obtaining informed consent;
or both
(ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.
(iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:
(AA) that occur in the course of surgery; or
(BB) whose exigency precludes obtaining informed consent;
or both
(iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:
(AA) Objects intentionally implanted as part of a planned intervention.
(BB) Objects present before surgery that were intentionally retained.
(CC) Retention of broken microneedles
(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been

carried out.

(B) The following product or device events:

(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.

(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:

(AA) Catheters.

(BB) Drains and other specialized tubes.

(CC) Infusion pumps.

(DD) Ventilators.

(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center. Excluded are deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(C) The following patient protection events:

(i) Infant discharged to the wrong person.

(ii) Patient death or serious disability associated with patient elopement.

(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to the center. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the center.

(D) The following care management events:

(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:

(AA) drug;

(BB) dose;

(CC) patient;

(DD) time;

(EE) rate;

(FF) preparation; or

(GG) route of administration.

Excluded are reasonable differences in clinical judgment on drug selection and dose.

(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the center. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:

(AA) Pulmonary or amniotic fluid embolism.

(BB) Acute fatty liver of pregnancy.

(CC) Cardiomyopathy.

(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the center.

(v) Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates.

(vi) Stage 3 or 4 pressure ulcers acquired after admission to the center. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable due to the presence of eschar.

(vii) Patient death or serious disability due to joint movement therapy performed in the center.

(E) The following environmental events:

(i) Patient death or serious disability associated with an electric shock while being cared for in the center. Excluded are events involving planned treatment, such as electrical countershock.

(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:

(AA) contains the wrong gas; or

(BB) is contaminated by toxic substances.

(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the

center.

(iv) Patient death associated with a fall while being cared for in the center.

(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the center.

(F) The following criminal events:

(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.

(ii) Abduction of a patient of any age.

(iii) Sexual assault on a patient within or on the grounds of the center.

(iv) Death or significant injury of a patient or staff member resulting from a physical assault (i.e. battery) that occurs within or on the grounds of the center.

(2) A process for reporting to the department each serious adverse event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.

(b) Subject to subsection (e), the process for determining the occurrence of the serious adverse events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the serious adverse events listed in subsection (a)(1) within the center in a timely manner.

(c) Subject to subsection (e), the process for reporting the occurrence of a serious adverse event listed in subsection (a)(1) shall comply with the following:

(1) The report shall:

(A) be made to the department;

(B) be submitted not later than fifteen (15) working days after the serious adverse event is determined to have occurred by the center's quality assessment and improvement program;

(C) be submitted not later than six (6) months after the potential event is brought to the program's attention; and

(D) identify the serious adverse event and the center, but shall not include any identifying information for any:

(i) patient;

(ii) individual licensed under IC 25; or

(iii) center employee involved;

or any other information.

(2) A potentially reportable serious adverse event may be identified by a center that receives a patient as a transfer from another health care facility subject to a serious adverse event requirement or admits a patient subsequent to discharge from another health care facility subject to a serious adverse event requirement. In the event that a center identifies a potentially reportable event originating from another health care facility subject to a serious adverse event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a serious adverse reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(d) The center's report of a serious adverse event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of such serious adverse events occurring within each center. The department's public report will be issued not less frequently than annually.

(e) Any serious adverse event listed in subsection (a)(1) that:

(1) is determined to have occurred within the center between:

(A) January 1, 2006; and

(B) the effective date of this rule; and

(2) has not been previously reported;

must be reported within five (5) days of the effective date of this rule. *(Indiana State Department of Health; 410 IAC 15-2.4-2.2)*

SECTION 2. 410 IAC 26-1-1 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-1-1 Applicability
Authority: IC 16-21-1-7; IC 16-21-1-8; IC 16-21-1-9
Affected: IC 16-19-3; IC 16-21-1

Sec. 1. The definitions in this rule apply throughout this article **except as otherwise indicated**. *(Indiana State Department of Health; 410 IAC 26-1-1; filed May 11, 2006, 9:36 a.m.; 29 IR 3355)*

SECTION 3. 410 IAC 26-1-3.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-3.5 "ASA Class I patient" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 3.5. "ASA Class I patient" means a normal, healthy patient. *(Indiana State Department of Health; 410 IAC 26-1-3.5)*

SECTION 4. 410 IAC 26-1-4.6 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-4.6 "Biologics" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 4.6 "Biologics" means a biological product, such as:
(1) a globulin;
(2) a serum;
(3) a vaccine;
(4) an antitoxin;
(5) blood; or
(6) an antigen;
used in the prevention or treatment of disease. *(Indiana State Department of Health; 410 IAC 26-1-4.6)*

SECTION 5. 410 IAC 26-1-4.8 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-4.8 "Burn" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1
Sec. 4.8. "Burn" means any injury or damage to the tissues of the body caused by exposure to any of the following:
(1) Fire.
(2) Heat.
(3) Chemicals.
(4) Electricity.
(5) Radiation.
(6) Gases.
(Indiana State Department of Health; 410 IAC 26-1-4.8)

SECTION 6. 410 IAC 26-1-9.3 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-9.5 "Elopement" defined
Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1

Sec. 9.5. "Elopement" means any situation in which a registered or admitted patient, excluding events involving adults with decision making capacity, leaves the clinic without staff being aware that the patient has done so. *(Indiana State Department of Health; 410 IAC 26-1-9.5)*

SECTION 7. 410 IAC 26-1-12.4 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-12.4 "Hypoglycemia" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 12.4. "Hypoglycemia" means a physiologic state in which:
(1) the blood sugar falls below sixty (60) mg/dl (forty (40) mg/dl in neonates); and
(2) physiological or neurological, or both, dysfunction begins.
(Indiana State Department of Health; 410 IAC 26-1-12.4)

SECTION 8. 410 IAC 26-1-12.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-12.5 "Immediately postoperative" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 12.5. "Immediately postoperative" means within twenty-four (24) hours after either of the following:
(1) Induction of anesthesia (if surgery or other invasive procedure is not completed).
(2) Completion of surgery or other invasive procedure.
(Indiana State Department of Health; 410 IAC 26-1-12.5)

SECTION 9. 410 IAC 26-1-12.6 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-12.6 "Informed consent" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 12.6. "Informed consent" means a patient's authorization or agreement to undergo surgery or other invasive procedure that is based upon communication between a patient and his or her physician regarding the surgery or other invasive procedure. *(Indiana State Department of Health; 410 IAC 26-1-12.6)*

SECTION 10. 410 IAC 26-1-12.7 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-12.7 "Intended use" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 12.7. "Intended use" means the use of a device as described on the label and associated materials provided by the device's manufacturer. *(Indiana State Department of Health; 410 IAC 26-1-12.7)*

SECTION 11. 410 IAC 26-1-12.8 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-12.8 "Joint movement therapy" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 12.8. "Joint movement therapy" means all types of manual techniques, to include:

(1) mobilization (movement of the spine or a joint within its physiologic range of motion);

(2) manipulation (movement of the spine or a joint beyond its normal voluntary physiologic range of motion); or

(3) any other type of manual musculoskeletal therapy;

regardless of their precise anatomic and physiologic focus or their discipline of origin. *(Indiana State Department of Health; 410 IAC 26-1-12.8)*

SECTION 12. 410 IAC 26-1-12.9 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-12.9 "Kernicterus" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 12.9. "Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage. *(Indiana State Department of Health; 410 IAC 26-1-12.9)*

SECTION 13. 410 IAC 26-1-13.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-13.5 "Low-risk pregnancy" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.5. "Low-risk pregnancy" means a woman sixteen (16) to thirty-nine (39) years of age, with no previous diagnosis of any of the following:

(1) Essential hypertension.
(2) Renal disease.
(3) Collagen-vascular disease.
(4) Liver disease.
(5) Preeclampsia.
(6) Cardiovascular disease.
(7) Placenta previa.
(8) Multiple gestation.
(9) Intrauterine growth retardation.
(10) Smoking.
(11) Pregnancy-induced hypertension.
(12) Premature rupture of membranes.
(13) Other previously documented condition that poses a high risk of pregnancy-related mortality.
(Indiana State Department of Health; 410 IAC 26-1-13.5)

SECTION 14. 410 IAC 26-1-17.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-17.5 "Serious disability" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 17.5. "Serious disability" means either of the following:

(1) Significant loss of function including sensory, motor, physiologic, or intellectual impairment:
(A) not present on admission and requiring continued treatment; or
(B) for which there is a high probability of long term or permanent lifestyle change at discharge.

(2) Unintended loss of a body part.
(Indiana State Department of Health; 410 IAC 26-1-17.5)

SECTION 15. 410 IAC 26-1-17.6 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-17.6 "Sexual assault" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1; IC 35-42-4; IC 35-46-1

Sec. 17.6. "Sexual assault" means a crime included under IC 35-42-4 or IC 35-46-1-3.
(*Indiana State Department of Health; 410 IAC 26-1-17.6)*

SECTION 16. 410 IAC 26-1-17.8 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-17.8 "Surgery or other invasive procedure" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 17.8. "Surgery or other invasive procedure", for purposes of 410 IAC 26-6-2, means surgical or other invasive procedures that involves a skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure begins at the time of the skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. Such procedures include, but are not limited to:
(1) Open or percutaneous surgical procedures.
(2) Percutaneous aspiration.
(3) Selected injections.
(4) Biopsy.
(5) Percutaneous cardiac and vascular diagnostic or interventional procedures.
(6) Laparoscopies.
(7) Endoscopies.
(8) Colonoscopies.
The term excludes intravenous therapy, venipuncture for phlebotomy, or diagnostic tests without intravenous contrast agents.
(Indiana State Department of Health; 410 IAC 26-1-17.8)

SECTION 17. 410 IAC 26-1-19 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-19 "Toxic substance" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 19. "Toxic substance" means chemicals that are present in sufficient concentration to pose a hazard to human health.
(Indiana State Department of Health; 410 IAC 26-1-19)

SECTION 18. 410 IAC 26-6-2 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-6-2 Reporting serious adverse events
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 2. (a) The clinic's quality assessment and improvement program under section 1 of this rule shall include the following:
(1) A process for determining the occurrence of the following serious adverse events within the clinic:
(A) The following surgical events:

(i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;

or both.

(ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.

(iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;

or both.

(iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:

(AA) Objects intentionally implanted as part of a planned intervention.

(BB) Objects present before surgery that were intentionally retained.

(CC) Retention of broken microneedles.

(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.

(B) The following product or device events:

(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the clinic. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.

(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:

(AA) Catheters.

(BB) Drains and other specialized tubes.

(CC) Infusion pumps.

(DD) Ventilators.

(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the clinic. Excluded are deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(C) The following patient protection events:

(i) Infants discharged to the wrong person.

(ii) Patient death or serious disability associated with patient elopement.

(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the clinic, defined as events that result from patient actions after admission to the clinic. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the clinic.

(D) The following care management events:

(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:

(AA) drug;

(BB) dose;

(CC) patient;

(DD) time;

(EE) rate;

(FF) preparation; or

(GG) route of administration.

Excluded are reasonable differences in clinical judgment on drug selection and dose.

(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the clinic. Included are events that occur within forty-two (42) days post-delivery. Excluded are deaths from any of the following:

(AA) Pulmonary or amniotic fluid embolism.

(BB) Acute fatty liver of pregnancy.

(CC) Cardiomyopathy.

(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the clinic.

(v) Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates.

(vi) Stage 3 or 4 pressure ulcers acquired after admission to the clinic. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable due to the presence of eschar.

(vii) Patient death or serious disability due to joint movement therapy performed in the clinic.

(E) The following environmental events:

(i) Patient death or serious disability associated with an electric shock while being cared for in the clinic. Excluded are events involving planned treatment, such as electrical countershock.

(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:

(AA) contains the wrong gas; or

(BB) is contaminated by toxic substances.

(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the clinic.

(iv) Patient death associated with a fall while being cared for in the clinic.

(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the clinic.

(F) The following criminal events:

(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.

(ii) Abduction of a patient of any age.

(iii) Sexual assault on a patient within or on the grounds of the clinic.

(iv) Death or significant injury of a patient or staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the clinic.

(2) A process for reporting to the department each serious adverse event listed in subdivision (1) that is determined by the clinic's quality assessment and improvement program to have occurred within the clinic.

(b) Subject to subsection (e), the process for determining the occurrence of the serious adverse events listed in subsection (a)(1) by the clinic's quality assessment and improvement program shall be designed by the clinic to accurately determine the occurrence of any of the serious adverse events listed in subsection (a)(1) within the clinic in a timely manner.

(c) Subject to subsection (e), the process for reporting the occurrence of a serious adverse event listed in subsection (a)(1) shall comply with the following:

(1) The report shall:

(A) be made to the department;

(B) be submitted not later than fifteen (15) working days after the serious adverse event is determined to have occurred by the clinic's quality assessment and improvement program;

(C) be submitted not later than six (6) months after the potential event is brought to the program's attention; and

(D) identify the serious adverse event and the clinic, but shall not include any identifying information for any:

(i) patient;

(ii) individual licensed under IC 25; or

(iii) clinic employee involved;

or any other information.

(2) A potentially reportable serious adverse event may be identified by a clinic that receives a patient as a transfer from another health care facility subject to a serious adverse event requirement or admits a patient subsequent to discharge from another health care facility subject to a serious adverse event requirement. In the event that a clinic identifies a potentially reportable event originating from another health care facility subject to a serious adverse event

requirement, the identifying clinic shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a serious adverse reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(d) The clinic's report of a serious adverse event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of such serious adverse events occurring within each clinic. The department's public report will be issued not less frequently than annually.

(e) Any serious adverse event listed in subsection (a)(1) that:

(1) is determined to have occurred within the clinic between:

(A) January 1, 2006; and

(B) the effective date of this rule; and

(2) has not been previously reported;

must be reported within five (5) days of the effective date of this rule. *(Indiana State Department of Health; 410 IAC 26-6-2)*

SECTION 19. 410 IAC 27-1-1 IS AMENDED TO READ AS FOLLOWS:

410 IAC 27-1-1 Applicability

Authority:IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-19-3; IC 16-21-1

Sec. 1. The definitions in this rule apply throughout this article **except as otherwise indicated**. *(Indiana State Department of Health; 410 IAC 27-1-1; filed Feb 3, 2006, 2:00 p.m.: 29 IR 1904)*

SECTION 20. 410 IAC 27-1-1.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-1.5 "ASA Class I patient" defined

Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1

Sec. 1.5. "ASA Class I patient" means a normal, healthy patient. *(Indiana State Department of Health; 410 IAC 27-1-1.5)*

SECTION 21. 410 IAC 27-1-2.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-2.5 "Biologics" defined

Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1

Sec. 2.5 "Biologics" means a biological product, such as:

(1) a globulin;

(2) a serum;

(3) a vaccine;

(4) an antitoxin;

(5) blood; or

(6) an antigen;

used in the prevention or treatment of disease. *(Indiana State Department of Health; 410 IAC 27-1-2.5)*

SECTION 22. 410 IAC 27-1-3.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-3.5 "Burn" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 3.5. "Burn" means any injury or damage to the tissues of the body caused by exposure to any of the following:
(1) Fire.
(2) Heat.
(3) Chemicals.
(4) Electricity.
(5) Radiation.
(6) Gases.
(Indiana State Department of Health; 410 IAC 27-1-3.5)

SECTION 23. 410 IAC 27-1-9.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-9.5 "Elopement" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 9.5. "Elopement" means any situation in which a registered or admitted patient, excluding events involving adults with decision making capacity, leaves the center without staff being aware that the patient has done so. *(Indiana State Department of Health; 410 IAC 27-1-9.5)*

SECTION 24. 410 IAC 27-1-13.4 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-13.3 "Hyperbilirubinemia" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.3. "Hyperbilirubinemia" means total serum bilirubin levels greater than twenty-five (25) mg/dl in a neonate. *(Indiana State Department of Health; 410 IAC 27-1-13.3)*

SECTION 25. 410 IAC 27-1-13.4 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-13.4 "Hypoglycemia" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.4. "Hypoglycemia" means a physiologic state in which:
(1) the blood sugar falls below sixty (60) mg/dl (forty (40) mg/dl in neonates); and
(2) physiological or neurological, or both, dysfunction begins.
(Indiana State Department of Health; 410 IAC 27-1-13.4)

SECTION 26. 410 IAC 27-1-13.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-13.5 "Immediately postoperative" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.5. "Immediately postoperative" means within twenty-four (24) hours after either of the following:

(1) Induction of anesthesia (if surgery or other invasive procedure is not completed).
(2) Completion of surgery or other invasive procedure.
(Indiana State Department of Health; 410 IAC 27-1-13.5)

SECTION 27. 410 IAC 27-1-13.6 IS ADNDED TO READ AS FOLLOWS:

410 IAC 27-1-13.6 "Informed consent" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.6. "Informed consent" means a patient's authorization or agreement to undergo surgery or other invasive procedure that is based upon communication between a patient and his or her physician regarding the surgery or other invasive procedure. *(Indiana State Department of Health; 410 IAC 27-1-13.6)*

SECTION 28. 410 IAC 27-1-13.7 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-13.7 "Intended use" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.7. "Intended use" means the use of a device as described on the label and associated materials provided by the device's manufacturer. *(Indiana State Department of Health; 410 IAC 27-1-13.7)*

SECTION 29. 410 IAC 27-1-13.8 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-13.8 "Joint movement therapy" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.8. "Joint movement therapy" means all types of manual techniques, to include:

(1) mobilization (movement of the spine or a joint within its physiologic range of motion);
(2) manipulation (movement of the spine or a joint beyond its normal voluntary physiologic range of motion); or
(3) any other type of manual musculoskeletal therapy;

regardless of their precise anatomic and physiologic focus or their discipline of origin. *(Indiana State Department of Health; 410 IAC 27-1-13.8)*

SECTION 30. 410 IAC 27-1-13.9 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-13.9 "Kernicterus" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.9. "Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage. *(Indiana State Department of Health; 410 IAC 27-1-13.9)*

SECTION 31. 410 IAC 27-1-15.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-15.5 "Low-risk pregnancy" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 15.5. "Low-risk pregnancy" means a woman sixteen (16) to thirty-nine (39) years of age, with no previous diagnosis of any of the following:

(1) Essential hypertension.
(2) Renal disease.
(3) Collagen-vascular disease.
(4) Liver disease.
(5) Preeclampsia.
(6) Cardiovascular disease.
(7) Placenta previa.
(8) Multiple gestation.
(9) Intrauterine growth retardation.
(10) Smoking.
(11) Pregnancy-induced hypertension.
(12) Premature rupture of membranes.
(13) Other previously documented condition that poses a high risk of pregnancy-related mortality.

(Indiana State Department of Health; 410 IAC 27-1-15.5)

SECTION 32. 410 IAC 27-1-16.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-16.5 "Neonates" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 16.5. "Neonates" means infants in the first twenty-eight (28) days of life. *(Indiana State Department of Health; 410 IAC 27-1-16.5)*

SECTION 33. 410 IAC 27-1-21.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-21.5 "Serious disability" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 21.5. "Serious disability" means either of the following:
(1) Significant loss of function including sensory, motor, physiologic, or intellectual impairment:
(A) not present on admission and requiring continued treatment; or
(B) for which there is a high probability of long term or permanent lifestyle change at discharge.
(2) Unintended loss of a body part.

(Indiana State Department of Health; 410 IAC 27-1-21.5)

SECTION 34. 410 IAC 27-1-21.6 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-21.6 "Sexual assault" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1; IC 35-42-4; IC 35-46-1

Sec. 21.6. "Sexual assault" means a crime included under IC 35-42-4 or IC 35-46-1-3.

(*Indiana State Department of Health; 410 IAC 27-1-21.6)*

SECTION 35. 410 IAC 27-1-23 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-23 "Surgery or other invasive procedure" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 23. "Surgery or other invasive procedure" means, for purposes of 410 IAC 27-6-2, surgical or other invasive procedures that involves a skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure begins at the time of the skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. Such procedures include, but are not limited to:

(1) Open or percutaneous surgical procedures.
(2) Percutaneous aspiration.
(3) Selected injections.
(4) Biopsy.
(5) Percutaneous cardiac and vascular diagnostic or interventional procedures.
(6) Laparoscopies.
(7) Endoscopies.
(8) Colonoscopies.

The term excludes intravenous therapy, venipuncture for phlebotomy, or diagnostic tests without intravenous contract agents.
(Indiana State Department of Health; 410 IAC 27-1-23)

SECTION 36. 410 IAC 27-1-24 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-1-24 "Toxic substance" defined
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 24. "Toxic substance" means chemicals that are present in sufficient concentration to pose a hazard to human health.
(Indiana State Department of Health; 410 IAC 27-1-24)

SECTION 37. 410 IAC 27-6-2 IS ADDED TO READ AS FOLLOWS:

410 IAC 27-6-2 Reporting serious adverse events
Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 2. (a) The center's quality assessment and improvement program under section 1 of this rule shall include the following:

(1) A process for determining the occurrence of the following serious adverse events within the center:
(A) The following surgical events:
(i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:
(AA) that occur in the course of surgery; or
(BB) whose exigency precludes obtaining informed consent;
or both.
(ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.
(iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:
(AA) that occur in the course of surgery; or
(BB) whose exigency precludes obtaining informed consent;
or both.
(iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:
(AA) Objects intentionally implanted as part of a planned intervention.
(BB) Objects present before surgery that were intentionally retained.

(CC) Retention of broken microneedles.

(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.

(B) The following product or device events:

(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.

(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:

(AA) Catheters.

(BB) Drains and other specialized tubes.

(CC) Infusion pumps.

(DD) Ventilators.

(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center. Excluded are deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(C) The following patient protection events:

(i) Infant discharged to the wrong person.

(ii) Patient death or serious disability associated with patient elopement.

(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to the center. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the center.

(D) The following care management events:

(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:

(AA) drug;

(BB) dose;

(CC) patient;

(DD) time;

(EE) rate;

(FF) preparation; or

(GG) route of administration.

Excluded are reasonable differences in clinical judgment on drug selection and dose.

(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the center. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:

(AA) Pulmonary or amniotic fluid embolism.

(BB) Acute fatty liver of pregnancy.

(CC) Cardiomyopathy.

(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the center.

(v) Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates.

(vi) Stage 3 or 4 pressure ulcers acquired after admission to the center. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable due to the presence of eschar.

(vii) Patient death or serious disability due to joint movement therapy performed in the center.

(E) The following environmental events:

(i) Patient death or serious disability associated with an electric shock while being cared for in the center. Excluded are events involving planned treatment, such as electrical countershock.

(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:

(AA) contains the wrong gas; or

(BB) is contaminated by toxic substances.

(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the center.

(iv) Patient death associated with a fall while being cared for in the center.

(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the center.

(F) The following criminal events:

(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.

(ii) Abduction of a patient of any age.

(iii) Sexual assault on a patient within or on the grounds of the center.

(iv) Death or significant injury of a patient or staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the center.

(2) A process for reporting to the department each serious adverse event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.

(b) Subject to subsection (e), the process for determining the occurrence of the serious adverse events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the serious adverse events listed in subsection (a)(1) within the center in a timely manner.

(c) Subject to subsection (e), the process for reporting the occurrence of a serious adverse event listed in subsection (a)(1) shall comply with the following:

(1) The report shall:

(A) be made to the department;

(B) be submitted not later than fifteen (15) working days after the serious adverse event is determined to have occurred by the center's quality assessment and improvement program;

(C) be submitted not later than six (6) months after the potential event is brought to the program's attention; and

(D) identify the serious adverse event and the center, but shall not include any identifying information for any:

(i) patient;

(ii) individual licensed under IC 25; or

(iii) center employee involved;

or any other information.

(2) A potentially reportable serious adverse event may be identified by a center that receives a patient as a transfer from another health care facility subject to a serious adverse event requirement or admits a patient subsequent to discharge from another health care facility subject to a serious adverse event requirement. In the event that a center identifies a potentially reportable event originating from another health care facility subject to a serious adverse event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a serious adverse reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(d) The center's report of a serious adverse event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of such serious adverse events occurring within each center. The department's public report will be issued not less frequently than annually.

(e) Any serious adverse event listed in subsection (a)(1) that:

(1) is determined to have occurred within the center between:

(A) January 1, 2006; and

(B) the effective date of this rule; and

(2) has not been previously reported;

must be reported within five (5) days of the effective date of this rule. *(Indiana State Department of Health; 410 IAC 27-6-2)*